PROSPECTIVE RANDOMIZED COMPARISON OF PROSEAL LMA AND ENDOTRACHEAL TUBE FOR AIRWAY MANAGEMENT IN PEDIATRIC PATIENTS

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CERTIFICATE

This is to certify that the dissertation entitled, **"Prospective randomized comparison of Proseal LMA with Endotracheal tube for airway management in pediatric patients"** submitted by **DR. CHARULATHA. R** in partial fulfillment for the award of degree of doctor of medicine in anesthesiology by The Tamilnadu Dr. M. G. R Medical University, Chennai is a bonafide record done by her in the Institute of Anesthesiology and Critical Care, Madras Medical College during academic year 2009-2012

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CONTENT

INTRODUCTION

Dr. Archie Brain developed a new way of linking artificial and anatomical airway, between 1981 and 1987.This new concept called Laryngeal Mask Airway combined the advantages of a non invasive facemask and the more invasive tracheal tube.

Originally LMA was recommended as a better alternative to the face mask. But ever since its development the LMA has challenged the assumption that tracheal intubation is the only acceptable way to maintain a clear airway and provide positive pressure ventilation.

Though LMA provided all the above advantages, the risk of gastric distension, pulmonary aspiration of gastric contents and fear of inadequate ventilation acted as a deterrent to the widespread use of LMA.

To overcome the above complications, Dr. Archie Brain designed the Proseal Laryngeal Mask Airway (PLMA) in 2001, with modifications designed to enable separation of gastro intestinal and respiratory tract, improve airway seal, enable positive pressure ventilation and diagnose mask displacement. A Drain tube (DT) enables diagnosis of mask misplacement, reduces risk of gastric insufflation, regurgitation and aspiration of gastric contents.

Prior to the advent of Proseal LMA, the endotracheal tube was the standard way of securing airway in children.

Proseal LMA is the new airway device that forms a more effective glottic seal and it facilitates passage of a drain tube. It probably provides protection against regurgitation and prevents gastric insufflation when correctly placed.

With this background this study was conceptualized to compare endotracheal tube and Proseal LMA for airway management in pediatric patients requiring elective surgery under general anaesthesia.

PROSEAL LMA

The LMA Proseal was developed in 2001 by Dr. Archie Brain by incorporating a gastric drain tube passing from distal end of the cuff to the atmosphere. The LMA Proseal allows maximum airway seal during positive pressure ventilation as compared with other LMA devices (40-60 cm H20) and allows passive (regurgitation) and active (drain tube insertion) emptying of the stomach.

The LMA – Proseal has four main parts the cuff, inflation line with pilot balloon, airway tube and drain tube. All components are made from silicone and are latex free. The Airway tube of LMA Proseal is shorter and smaller in diameter than that of the LMA – Classic and is wire reinforced which makes it more flexible. The LMA – Proseal has a deeper bowl than the LMA – Classic and does not have aperture bars. There is a bite block between the tubing at the level where the teeth would contact the device. The tip of the Proseal LMA lacks the semi rigid back plate of LMA classic.

The drain tube is parallel and lateral to the airway tube until it enters the cuff bowl, where it continues to an opening in the tip that is sloped anteriorly. When the LMA – Proseal is correctly positioned, the cuff tip lies behind the cricoid cartilage at the origin of the esophagus. It allows liquid and gases to escape from the stomach, reduces the incidence of gastric insufflation and pulmonary aspiration, allows

devices to pass into the esophagus and provides information about the LMA Proseal position.

The drain tube is designed to prevent the epiglottis from occluding the airway tube, eliminating the need for aperture bars. A plastic supporting ring around the distal drain tube prevents the tube from collapsing when the cuff is inflated.

The LMA Proseal has a second dorsal cuff. This pushes the mask anteriorly to provide a better seal around the glottic aperture and helps to anchor the device in place. The dorsal cuff is not present on sizes 1 ½ - 2 ½.

Modified Feature from the classic LMA	Intended Purpose
The second cuff attached to dorsal surface	To improve seal by pushing the ventral cuff.
The ventral cuff that is larger proximally	To form a better seal by plugging gaps in the proximal pharynx.
A large conical shaped distal cuff	To form a better seal with the hypo pharynx. To reduce the risk of down folded epiglottis obstructing the distal aperture
A parallel, narrow bore, double tube configuration	To increase stability To improve seal by allowing the tongue to form a more effective plug.
A flexible, wire reinforced airway tube	To prevent airway tube from kinking.
A drainage channel to facilitate gastric tube insertion.	To divert regurgitated fluid away from the respiratory tract. To prevent gastric insufflation.
A drainage tube distal aperture that is sloped anteriorly.	To allow the deflated tip to form a fine edge for insertion.
A plastic supporting ring around the distal drainage tube.	To prevent the drainage tube from collapsing when the cuff is inflated.
Drainage tube that passes within the bowl.	To avoid altering the external shape of the cuff. To function as mark aperture bar for accessory vent.
A rectangular depression in the proximal bowl tube	To function as an accessory ventilation channel. To prevent pooling of secretions at the distal aperture of the airway.

Built-in-bite block	To prevent damage to the device during biting. To provide information about depth of insertion. To help fuse airway and drain tube together
Introducer strap	To prevent finger from slipping off the tube. To keep proximal cuff in the midline.
No back plate	To reduce and allow room for the dorsal cuff.
No mask aperture bar	To reduce resistance to gas flow

Proseal LMA Sizes:

LMA size	Patient Wt(kg)	Max cuff vol(ml)	Max size of gastric tube (Fr)	Largest tracheal tube(ID in mm) Uncuffed
1.5	5-10	7	10	4.0
2	10-20	10	10	4.0
2.5	20-30	14	14	4.5
3	30-50	20	16	5.0
4	50-70	30	16	5.0
5	70-100	40	18	6.0

INSERTION TECHNIQUE

There are three primary insertion techniques for the Proseal LMA:

1) Digital insertion, which is similar to the Classic LMA, but a lateral approach is required more frequently;

2) Introducer-guided insertion, which allows the head and neck are in the neutral position;

3) Gum elastic bougie guided insertion, which guides the Proseal around the oropharyngeal inlet and into the hypopharynx.

A greater depth of inhaled and intravenous anaesthesia is required for insertion of Proseal LMA than LMA classic. The technique of Proseal LMA insertion is more demanding than that for classic LMA, but a high success rate can be achieved. This effort is rewarded by a superior quality of airway. Airway seal pressure is increased by upto 50 % than classic LMA, thus facilitating positive pressure ventilation and better airway protection.

As a routine after insertion and inflation of the PLMA cuff to 60 cm H_2O, the correct placement of the device is confirmed by several observations and certain specific tests designated to assess PLMA positioning and evaluate the ventilatory

and drain tube functions of the mask. These diagnostic tests are simple and quick to perform and the first five of the following are more popular.

1. Visual assessment of depth of insertion
2. Unobstructed inspiratory and expiratory flow
3. Suprasternal notch tap test
4. Gel displacement test
5. Passage of gastric tube/ polyvinyl chloride (PVC) catheter through drain tube
6. Soap bubble test
7. Thread test
8. Trachlight™ test
9. Maximum minute ventilation (MMV) test

After confirming correct positioning, the PLMA is properly secured to avoid dislodgement as its cuff is bulkier than that of the cLMA.

1. Visual assessment of depth of insertion

Assess for adequate depth of insertion by examining the relation of the integral bite block to the incisors. Ideally the bite block lies between the teeth but protrudes in case the PLMA is inadequately inserted. Stix and O'Connor in a study of 274 adults found that when the ProSeal LMA was correctly positioned, the midway point of the bite block was proximal to the incisors in 78% of women and 92% of men. A PLMA with its bite block lying entirely outside the mouth is almost unquestionably mal positioned.

2. Unobstructed inspiratory and expiratory flow

This is assessed by manually ventilating the patient, observing chest movements, capnography, expired tidal volume (V_T) of > 8m1/kg, and evaluating the compliance by feel of the bag. The reported incidence of airway obstruction with PLMA has been found to vary from 2-10%.Increased resistance is suspected with partial obstruction resulting from infolding of the PLMA cuff or down folding of epiglottis. The PLMA, with its large drain tube and cuff, may produce respiratory obstruction by displacing the cricoid cartilage anteriorly thereby exerting direct pressure on the arytenoid bodies and muscular processes.

3. Suprasternal notch tap test or Brimacombe bounce

The suprasternal notch tap test or the “Brimacombe bounce” confirms the location of the PLMA tip in the esophagus behind the cricoid cartilage. The test was first described by O'Connor et al in 2002. It involves tapping the suprasternal notch or cricoid cartilage, and observing simultaneous movement of a column of lubricant, or a soap bubble membrane at the proximal end of the drain tube. Both the structures lie in close proximity to the hypo pharynx, where the correctly placed distal cuff sits. The drain tube must be patent for the test to be positive. The test works by cuff compression causing drain tube compression within the drain tube, which in turn moves the lubricant or soap bubble. O'Connor et al reported a low false-negative rate for the suprasternal notch tap test in 50 adults, but false positives and negatives can occur. False positives can occur if the last 1-2 cm of the drain tube is folded over but some of the drain tube is still patent within the distal cuff. False negatives can occur if the esophagus is open, since this can weaken the pressure wave.

4. Gel Displacement Test

Water-soluble gel (0.5-1 ml) is placed at the proximal end of the drain tube so that it forms a column of about 2-3 cm. Minimal movement or gentle up and down movements indicates a normal position. However, gel ejection with gentle positive pressure ventilation (PPV), indicates a leak from the drain tube, signifying improper seal of device with the hypo pharynx. Thus, when positive, the test indicates airway leak through the drain tube.

5. Passage of gastric tube/ PVC catheter through drain tube to verify the patency of drain tube

The posterior folding of the mask tip is ruled out by the successful passage of a gastric tube or a PVC catheter through the drain tube.

6. Soap Bubble Test

In this test, soap bubble solution is placed over the tip of the drain tube and following observations may be made. When the tip of the PLMA is in the laryn-gopharynx, soap bubble solution column bubbles or the soap membrane bursts during positive pressure ventilation. When the PLMA tip enters the glottis, the trachea bronchial tree communicates directly to the drain tube. The drain tube transmits the airway pressures unless it is obstructed. The PLMA insertion into the glottis is diagnosed by watching either the formation of a spontaneous bubble which is blown away from drain tube port or the soap membrane oscillations seen with cardiac rhythm of the patient.

7. Thread test

A gauze thread or small piece of cotton held over the proximal end of a leaking drain tube can also be used to detect air leak from the drain tube.

8. Trachlight™

The Trachlight™ helps in quickly distinguishing glottic from esophageal location of the tip of the PLMA mask. Trachlight™ (Laerdal Medical, Wappingers Falls, NY, USA) after removing its stylet is passed through the drain tube just as for blind endotracheal intubation. This is a simple and reliable means of detecting a PLMA tip fold over. A dull glow in the anterior neck with passage of the Trachlight™ wand beyond the drain tube tip indicates correct alignment of the PLMA with the upper esophageal sphincter.

9. Maximum Minute Volume Ventilation (MMV)

The MMV test consists of manually hyperventilating an anaesthetized and paralyzed patient with a PLMA for 15 seconds and extrapolating the total exhaled volume to one minute which can be graded as follows.

Basal values 5-7 L/min

Critical value 6-12L/min, threshold for removal of Proseal LMA

Mean value 26-29L/min

The test is easy to perform and can be completed with equipment that is readily accessible to almost every anesthesiologist.

Anesthesiologists should be alerted to the potential for significant airway obstruction in any patient with a MMV less than 12 L/min. It is advisable to

remove the PLMA and use an alternative device before the initiation of surgery. In this scenario, one should not have a false sense of security due to the normal oxygen saturation as the latter does not guarantee the satisfactory elimination of CO_2. However, the decision to remove the PLMA should be based depending on the patient's physical status, nature, site and duration of surgery.

An incorrectly placed Proseal LMA will result in unreliable or obstructed ventilation. Correct placement of Proseal LMA should produce a leak – free seal around the glottis with the mask tip and the drain tube lying around the upper esophageal sphincter.

There are three important malpositions of the Proseal LMA.

1. The Proseal LMA may not be inserted sufficiently far, with the consequence that the tip of the drain tube lies within the pharynx. Positive pressure ventilation is ineffective because delivered gases pass out of the drain tube.

2. The tip of the Proseal LMA lies within the glottis, thereby obstructing ventilation and impairing function of the drain tube.

3. The tip may be folded over and obstruct ventilation and the drain tube.

Malposition should be corrected by repositioning the LMA, using a different insertion technique, or replacing it with an alternative airway device.

Initial checks of function are identical to those used with LMA classic. In particular, chest expansion should be good with reasonable airway pressure, and there should be no signs of airway obstruction, particularly slow refill of the reservoir bag.

The drain tube should be tested for patency. This can be done by passing a orodrain tube, flexible endoscope, or a lighted stylet through the drain tube. Easy passage indicates correct positioning. Difficulty suggests that Proseal should be repositioned, even if ventilation is satisfactory.

Disadvantages with LMA ProSeal:

The LMA Proseal is less suitable as an intubation device because of narrow airway tube. The high resistance associated with smaller lumen makes it less suitable for use with spontaneously breathing patients than other devices.

The LMA-Proseal takes slightly longer time to insert than the classic LMA in adults, although overall success is equivalent. The incidence of intraoperative complication and postoperative sore throat are similar.

In children, LMA-Proseal requires a greater depth of anaesthesia for insertion than does LMA-classic.

The LMA-Proseal can cause airway obstruction after insertion, either by compressing the supraglottis and glottic structures or by cuff in folding.

It may not be possible to insert a drain tube in some patients. This may be due to selection of too large a tube, inadequate lubrication, using a cooled gastric tube, cuff over inflation or malposition.

The LMA Proseal is relatively contraindicated for intraoral surgery because it cannot be moved easily around the mouth, the drain tube is vulnerable to occlusion, and larger proximal cuff would interfere with surgical field.

Pediatric Patients

The Proseal LMA provides a useful alternative for the tracheal tube when it is necessary to administer anaesthesia to children requiring general anaesthesia.

The Proseal LMA can be used for children with subglottic stenosis who are undergoing surgery not related to airway. The laryngeal mask has been used for high frequency oscillation for a premature infant.

The likelihood of floppy epiglottis being within the mask is greater than in adults.

Smaller children are more likely to have airway obstruction, greater inspiratory leak, and more complication and require higher ventilatory pressures than older children.

Sterilization

The LMAs and their accessories are supplied unsterile, and must be cleaned by hand washing or automatic washers and autoclaved at 135°C for 3-4 minutes (pre-vacuum and wrapped). The cuff should be fully deflated and dry before

autoclaving. Proseal requires more attention. A small pipe cleaner should be used to clean the drain tube and deflation of the Proseal cuff requires the deflation tool since residual air can accumulate in the dorsal cuff.

REVIEW OF LITERATURE

1. **Mamta G Patel et al** studied Proseal LMA and ET tube for airway management in children under general anaesthesia. They observed that changes in hemodynamic parameters were significant in ETT group and requirement of sevoflurane was less in the Proseal group. The incidence of complications like sore throat (13.3%) and coughing (12%) were higher in ETT group. This study published in Indian Journal of Anaesthesia Dec 2010 concluded that PLMA can be used as a safe and effective alternative device to endotracheal intubation in children.

2. **Lardner DR,Cox RG et al** compared a laryngeal mask airway and Proseal LMA in 51 children receiving neuromuscular blockade .This study published in Can J Anaesth 2008 Jan evaluated oropharyngeal leak pressure and gastric insufflation with both the devices using IPPV. There was no significant difference in oropharyngeal leak pressures and gastric insufflation was more common with Classic LMA (12/26/VS 2/25)

3. A randomized cross over study comparing pro seal and classic Laryngeal Mask airway in anesthetized children done by **Brimacombe et al** published in Br J Anaesth 2005 Dec concluded that ease of insertion, fiber optic position, frequency of mucosal trauma are similar for Proseal LMA and classic LMA but oropharyngeal leak pressure is higher and gastric insufflation less common for proseal LMA.

4. A review of Proseal Laryngeal Mask Airway in the management of difficult airway published **by T.M. Cook et al** in Anasthesia Sep 2005 showed that the Proseal LMA when correctly placed achieves a higher seal with airway than the cLMA and functionally separates gastrointestinal & respiratory tract. They concluded that Proseal LMA may have a role in difficult airway management.

5. **Brimacombe et al** compared Proseal Laryngeal Mask airway with nasal cannula for pediatric gastroscopy and showed that oxygen saturation was higher in the Proseal LMA group (100% VS 94<0.0006)and hypoxia occurred more frequently in the nasal cannula group (20% VS 0%).This study was published in Paediat Anaesth Oct 2006.

6. **Brimacombe et at** studied ease of insertion using duodenal tube guided insertion and oropharyngeal leak pressure difference between Proseal LMA and I gel in hundred and fifty non – paralyzed anesthetized females. Mean insertion times were similar for Proseal LMA and I gel (40 Vs 43 S), mean oropharyngeal leak pressures was 7 cm H_2O Higher with LMA Proseal ($P<0.0001$). This study was published in Anaesthesia September 2010.

7. **Dr. Birla Sharma et al** compared Proseal LMA and tracheal intubation in 100 patients undergoing laparoscopic surgery and observed that PLMA caused minimum hemodynamic responses to insertion, was a reliable airway management device ensuring adequate ventilation and provides an effective glottic seal. This study was published in Indian Anaesth 2003.

8. **Brimacombe et al** tested the hypothesis that response to jaw thrust is an effective predictor of insertion conditions for Proseal LMA. One hundred and sixty patients were studied (7 -18 yrs). Standard amount of jaw thrust was applied and lack of response predicted optimal insertion conditions in 84% of patients. This study was published in Middle East J Anaesth 2009 Feb.

9. **Shimbori et al** in British Journal of Anaesthesia 2004 compared Proseal LMA and LMA – Classic in children for ease of insertion, airway sealing pressure and fiber optic positioning. They observed no statistical difference between the two groups for success rates at first attempt of insertion, airway sealing pressures.

10. **Goldman et al in** Br J Anaesth 2005studied use of Proseal LMA for pressure controlled ventilation in pediatric patients and observed that PaO2 was higher when PEEP was used. PaO_2 (22.1Kpa VS 19.2 Kpa). Use of Proseal LMA allows use of PEEP for better gas exchange.

11. **Brimacombe et al** in Anaesthesiol Intensive med June 2003studied pharyngeal mucosal pressures with laryngeal tube airway versus Proseal LMA in fifteen fresh cadavers. Microchip pressure censors were attached to laryngeal tube and Proseal LMA. They suggested that mucosal pressures are highest for laryngeal tube airway and mucosal ischemic injury will be more common with laryngeal tube airway than with PLMA.

12. **Brimacombe et al** in Br.J.Anaesth Oct 2007_studied two hundred consecutive female patients undergoing routine breast and gynecological surgery and concluded that Proseal LMA reduced the absolute risk of postoperative nausea and vomiting by 40%. The frequency of airway morbidity and analgesic requirements is lower for Proseal LMA than tracheal tube.

13. **Brimacombe et al** in Anaesth analg Feb 2005 studied pressure support ventilation versus continuous positive airway pressure ventilation with the Proseal laryngeal mask airway in ASA physical status I children aged 1-7 years. They observed that PSV improves gas exchange and reduces work of breathing during Proseal laryngeal mask airway anaesthesia compared with CPAP because PSV group had lower $ETCO_2$, slower respiratory rate and higher expired tidal volume.

14. **Sinha et al** in Pediatric Anaesth Apr 2007 compared Proseal LMA with endotracheal tube in pediatric laparoscopy and they studied sixty ASA I and II children scheduled for elective laparoscopic surgery and concluded that there were no significant differences between both the groups. The pediatric LMA and tracheal tube have comparable ventilatory efficacy for elective short laparoscopic procedures.

15. **Lalwani et al** in Indian J Anaesth Nov 2010 studied Proseal LMA vs ETT in pediatric patients for short duration surgical procedures . They studied number of attempts for placement of devices, hemodynamic response and perioperative respiratory complications. Hemodynamic responses were significantly higher with endotracheal intubation and the incidence of postoperative respiratory complications was higher after extubation.

16. Proseal versus classic LMA for positive pressure ventilation during laparoscopic cholecystectomy. This study was published in Br J Anaesth Jun 2002. **Brimacombe et al** studied eighty anaesthetized paralyzed patient and concluded that ventilation was suboptimal with Classic LMA. The Proseal LMA is a more effective ventilatory device for laparoscopic cholecystectomy.

17. **Brimacombe et al** in Anesthesiology Feb 1999 studied pulmonary airway resistance with the endotracheal tube versus Laryngeal mask airway in paralyzed anesthetized adult patients. They used a pulmonary monitor with flow transducer and esophageal balloon to measure peak airway pressure and mean airway resistance. They concluded that peak airway pressure, mean airway resistance, device resistance and pulmonary airway resistance were greater for endotracheal tube (all $P<0.0001$)

18. **Brimacombe et al** studied the safety & efficacy of laryngeal mask airway in 1400 children in Anaesthesia 1996 and observed that placement was successful in 90% at the first attempt. Most problems came with the use of size 1 LMA ($P< 0.001$) there was no morbidity associated with the use of the device.

19. In the Euro J Anaesth Jan 2003

Brimacombe et al studied stability of LMA- Proseal and standard laryngeal mask airway in different head and neck positions, thirty paralyzed anaesthetized adult male patients were studied .The anatomical position of LMA Proseal and Classic LMA is stable in different positions but head neck flexion is associated with increase in oropharyngeal leak pressure and intracuff pressure.

20. **Brimacombe et al** in Can J Anaesth 1995 Nov studied the advantage of the LMA over the tracheal tube or facemask. Meta analyses done showed the following results. Advantages over tracheal tube are increased speed and ease of placement, reduced anaesthesia for airway tolerance, lower frequency of coughing during emergence, improved oxygen saturation during emergencies and lower incidence of sore throat in adults.

21. **Saraswat N et al** in Indian J Anaesth Mar 2011 compared Proseal LMA and endotracheal tube in patients undergoing laparoscopic surgeries .Mean airway pressure at which oropharyngeal leak occurred during leak test was 35 cm of H 20. Proseal LMA provided equally effective pulmonary ventilation despite high airway pressures without gastric distention, regurgitation & aspiration.

22. Korean J of Anaesthesiol Sept 2011.

Hahck soo Park et al studied the effect of head rotation on efficiency of ventilation and cuff pressure using PLMA in seventy seven pediatric patients. They concluded that although cuff pressure and tidal volume of PLMA were changed significantly after turning head from neutral position to side, readjustment of cuff pressure can make PLMA useful & successful in pediatric patients.

23. **Brimacombe et al** compared laryngeal mask airway with Proseal LMA in ninety three paralyzed anaesthetized patients in Anaesthesia 2009 Jan and they concluded that insertion, drain tube placement, fiber optic placement were similar for LMA Proseal and LMA supreme but oropharyngeal leak pressure and intracuff pressure are higher for Proseal LMA.

24. **Brimacombe et al** did a retrospective audit of Proseal LMA in prone patients which was published in Anaesth Intensive Care Apr 2007. They described use of Proseal LMA in 245 healthy adults in prone position. Ventilation was successful in all patients. They suggested that insertion and maintenance of anesthesia with Proseal LMA is feasible in prone position by experienced users.

25. **Brimacombe et al** assessed performance of size 2 and size 3 Proseal in terms of insertion success, efficacy of seal, tidal volume which was published in Paediatr Anaesth 2005 March. The first time and overall insertion success rate was 84 and 100% respectively. Despite the lack of a dorsal cuff, the performance of size 2 was similar to size 3 PLMA in age groups tested.

26. **Brimacombe et al** did a multicenter trial comparing Proseal LMA and classic LMA in anesthetized, non paralyzed patients which was published in Anesthesiology 2002. They studied three hundred eighty four non paralyzed anesthetized adult patients and concluded that LMA classic is easier to insert and PLMA forms a better seal and facilities easier quicker orogastric tube placement.

27. **Anaesth Analog 2000**

B**rimacombe et al** did a randomized cross – over cadaver study to determine whether Proseal LMA prevents aspiration of regurgitated fluid. Esophageal pressure was increased in 2 cm H_2O increments. They concluded that the correctly placed PLMA allows fluid in the esophagus to bypass the pharynx and mouth when the drain tube is open.

28. **Sarkar et al** studied the feasibility of using the Proseal laryngeal mask airway for airway maintenance during bronchoscopy guided percutaneous

tracheostomy. This study published in Indian J Crit care medicine 2010 Oct concluded that proseal LMA provides a reliable airway and allows effective ventilation during percutaneous tracheotomy. The passage of a fiberscope through Proseal LMA and glottis is easy and provides a clear view of the upper trachea.

29. **Can J Anaesth 2005 Aug – Sep.**

Cook et al did a analysis of published literature relating to Proseal LMA. Compared to cLMA, PLMA insertion takes a few seconds longer. Evidence suggests that Proseal LMA reduces aspiration risk compared with CLMA. PLMA use is associated with less coughing and less hemodynamic disturbance.

30. **Br J Anaesth May 2006**

Brain et al described the Proseal LMA as a LMA that incorporates a second tube placed lateral to the airway tube. A preliminary crossover comparison with the standard mask in 30 adult female patients showed no difference in insertion, trauma or quality of airway. At 60 CM H_2O the Proseal LMA gave twice the seal pressure of the standard device ($P< 0.0001$).

AIM OF THE STUDY

To evaluate the advantages and disadvantages of PROSEAL LMA over Endotracheal tube (ETT) for general anaesthesia in pediatric patients in the following parameters.

1. Ease of insertion of airway device
2. No of attempts for insertion of airway device
3. Time taken for insertion of airway device
4. Ease of insertion of orogastric tube
5. No. Of attempts for insertion of orogastric tube
6. Hemodynamic responses
7. Blood staining of devices
8. Incidence of complications

MATERIALS AND METHODS

STUDY DESIGN

Randomized prospective single center trial

STUDY POPULATION

60 children

INCLUSION CRITERIA

- Elective pediatric patients requiring general anaesthesia
- Males and females
- ASA physical status 1 and 2
- Age 2- 6 yrs old
- Weighing 10 – 20 kgs
- Whose parents have given valid informed consent

EXCLUSION CRITERIA

- Children posted for emergency surgery
- Children with difficult airway

- Lack of written informed consent
- Children with cardio respiratory disease, URI, hiatus hernia , full stomach, history of convulsions

MATERIALS

Pediatric Proseal LMA size 2

- Drugs: Inj.Atropine, Inj. Fentanyl , Inj. Propofol Inj. Atracurium ,Emergency drugs, normal saline
- Macintosh laryngoscope with blade 1 and 2
- Endotracheal tubes of 3.5 mm ID to 5.0mm ID
- Monitors: ECG,NIBP,SPO2,ETCO2,precordial stethoscope

METHODOLOGY

- Pre – medication : Inj. Atropine 20 micg/kg , Inj. Fentanyl 2 micg/ kg , Inj. Ondansetron 0.1 mg /kg
- Preoxygenation with 100 % o2 for five minutes
- Induction: Inj. Propofol 2 mg / kg + Inj. Atracurium 0.5 mg / kg
- Placement of endotracheal tube or Proseal LMA
- Anaesthesia maintained with N2O / O2 1:1 with Sevoflurane

- Inj. atracurium one – third of the initial dose repeated if necessary
- HR , BP , SPO2 noted immediately, first, third and fifth minute after insertion
- End of surgery : Reversal with Inj. Neostigmine 0.05 mg/kg + Inj Atropine 20 micg/ kg
- Perioperative respiratory complications noted on extubation

STUDY OUTCOME:

1. An effective airway on insertion of Proseal LMA was judged by bilateral equal air entry and normal thoraco - abdominal movement. If an effective airway could not be achieved the device was removed and three attempts were permitted before failure of insertion was recorded. If three attempts were unsuccessful either an alternative device was inserted or the trachea was intubated. The number of insertion attempts was recorded.

2. The ease of insertion of device was also recorded. Ease was defined as no resistance to insertion in the pharynx in a single maneuver. In a difficult insertion there were resistance to insertion or more than one maneuver were required for the correct placement of the device.

3. The ease of placement of orogastric tube was also recorded and its correct placement was confirmed by injection of air and epigastric auscultation or aspiration of gastric contents. Failure of orogastric tube placement was also recorded and it was defined as failure to advance the orogastric tube into the stomach within two attempts.

4. Time taken for insertion:

It is defined as the time elapsed between picking up of airway device in the hand and confirmation of the presence of bilateral equal air entry.

5. Haemodynamic responses:

The pulse rate and blood pressure were recorded before intubation, immediately post intubation and one minute, 3 minutes and 5 minutes post intubation.

6. Blood staining of the device:

At the end of the surgery the airway device was removed after adequate recovery. The presence or absence of blood on the device was noted.

7. Incidence of complications:

Laryngospasm were defined by rapid desaturation with absent air entry.

8. Hoarseness of voice was defined as being either change in the voice tone or a painful phonation.

CONDUCTION OF THE STUDY

After obtaining institutional ethical committee clearance, all children who were scheduled for elective surgery under general anaesthesia were screened for any co morbid illness and difficult airway. Age and weight were assessed. 60 Children satisfying the inclusion criteria were enrolled in the study. A written informed consent was obtained from the parents and the children were allocated randomly into two groups, PROSEAL LMA and ETT, with 30 each by using closed envelop method. The size of the airway was chosen in accordance to manufacturers recommendations.

The children were shifted inside the operating room and placed in supine position. ECG monitor, pulse oximetry and non invasive blood pressure monitor were connected. Baseline BP, HR and SPO2 were recorded.

All children were premedicated with Inj .Atropine 20 microgram /kg, Inj. Fentanyl 2 mcg/kg and Inj Ondansetron 0.1 mg /kg i. v.Preoxygenated with 100% oxygen at a flow rate of 4L/min for 5 minutes .Children were induced with Inj. Propofol 2 mg/kg.i.v , Inj. Atracurium 0.5mg/kg i.v.were administered for neuromuscular blockade after confirmation of successful manual bag-mask ventilation. Children were ventilated for 3 minutes. Pre intubation BP, HR and SPO2 were recorded.

In ETT group conventional laryngoscopy were performed with Macintosh 2 blade. The trachea was intubated using a single use endotracheal tube of appropriate size. In Proseal LMA group, size 2 Proseal LMA was inserted and is taped in position. The cuff is inflated with just enough air to achieve a seal sufficient to permit ventilation without leaks. Auscultation of bilateral air entry was noted as an indicator of effective ventilation. Otherwise the device was completely removed for another insertion attempt, with a maximum of 3 attempts allowed. The ease of insertion, no of attempts taken for successful placement and the time taken for insertion were noted in both the groups.

In Proseal LMA group, water soluble lubricant was placed in the proximal 1 cm of the drain tube, and the suprasternal notch test were performed to confirm the placement.

The gastric tubes were lubricated well. In Proseal LMA group the appropriate sized orogastric tube was inserted through the drain tube port. In ETT group the gastric tube was inserted nasally. Ease of insertion and no of attempts for successful insertion were noted. Gastric decompression was performed immediately after insertion. Anaesthesia was maintained with sevoflurane 1 % and O2:N2O at 1:1 ratio.

The blood pressure, heart rate and Spo2 were recorded immediately post intubation and after one minute, 3 minutes and 5 minutes. Muscle relaxation was maintained with Inj. Atracurium i.v. At the end of the surgery, the effects of neuromuscular blockade were reversed with Inj. Neostigmine 0.05mg/kg and Inj. Atropine 20 micro g/ kg iv.after turning the child to lateral position. The airway device was removed upon return of spontaneous breathing with the gastric tube in situ. The airway device was inspected for the presence of any visible blood.

The following complications were recorded – cough, stridor, laryngospasm and hypoxia. Children were evaluated for the presence of hoarseness of voice before leaving the operating room and 2 hours post operatively in the recovery room.

OBSERVATIONS AND RESULTS

All the qualitative data were analyzed using the chi- square test and the quantitative data using student' s unpaired t – test. The results were expressed as mean and standard deviation. P value < 0.05 were considered significant and p value <0.001 were taken as highly significant. P value was computed using Minitab version 15.0 and higher.

Table: 1 Demographic profile: Age

Group	No	Mean	SD	P value
PROSEAL-LMA	30	4.883	2.2425	0.929
ETT	30	4.942	2.7619	

The mean age of PROSEAL LMA group is 4.8 and ETT group is 4 .9 .The data is statistically not significant (p>0.05) and both groups are comparable in terms of age.

Table: 2 Demographic profile: WEIGHT

Group	No	Mean	SD	P value
PROSEAL LMA	30	12.93	3.513	0.272
ETT	30	13.93	3.473	

The mean weight of group PROSEAL LMA is 12.9and group ETT is 13.9

The data is statistically not significant (p>0.05) and these both groups are comparable in terms of weight.

Table: 3 Demographic profile: ASA PS Status

GROUP	ASA I		ASA II		P value
	No	%	No	%	
PROSEAL LMA	29	96.7	1	3.3	**0.554**
ETT	28	93.3	2	6.7	

In PROSEAL –LMA group 29 children were ASA I and 1 were ASA II children.

In ETT group 28 children were in ASA I and 2 were ASA II children.

The data is statistically not significant ($p>0.05$) and this both groups are comparable in terms of ASA PS Status.

Table: 4 Ease of insertion of airway device

Group	**No**	**Easy**		**Difficult**	
		No	%	No	%
PROSEAL LMA	30	30	100	0	0
ETT	30	30	100	-	-

There was no difficulty in insertion in both the groups

Qualitative data values were compared by chi-square test.

Table: 5 No of attempts –airway device

Group	No	Success in				P value
		1st attempt	%	2nd attempt	%	0.313
PROSEAL LMA	30	30	100	0		
ETT	30	29	96.7	1	3.3	

PROSEAL LMA insertion was successful in all children while one child in the endotracheal group required a second attempt. Statistical analysis reveals P value of 0.313. The two groups are statistically insignificant in no of attempts.

Table: 6 Time taken for insertion – airway device

Group	No	Mean	SD	P value
PROSEAL LMA	30	5.4	.747	<0.01
ETT	30	14.83	4.742	

The mean time taken for insertion in PROSEAL LMA group is 9.5 seconds and the mean time taken for insertion in ETT group is 14.83 seconds.

Student's t test reveals P value of <0.01 which is statistically significant.

Table: 7 No of attempts for insertion of gastric tube

Group	**No**	**Success in**				**P value**
		1st attempt	%	2nd attempt	%	0.076
Proseal LMA	30	27	90	3	10	
ETT	30	30	100	0	-	

In PROSEAL LMA group, gastric tube insertion was successful in all 27children in first attempt and three children in the second attempt. In ETT group, gastric tube insertion was successful in all the 30 children. Statistical analysis reveals P value of 0.076. The two groups are statistically insignificant in no of attempts for drain tube insertion.

Table: 11 Hemodynamic Responses

Heart Rate

	Group	No	Mean	SD	P value
Baseline	PROSEAL LMA	30	131.80	15.284	.085
	ETT	30	140.27	21.576	
Pre insertion	PROSEAL LMA	30	123.37	14.041	0.796
	ETT	30	124.53	20.209	
Post insertion at 0 min	PROSEAL LMA	30	122.70	9.444	.000
	ETT	30	135.07	15.268	
Post insertion at 1 min	PROSEAL LMA	30	121.83	9.742	0.001
	ETT	30	134.57	16.600	
Past insertion at 3 min	PROSEAL LMA	30	121.03	11.324	0.010
	ETT	30	131.60	19.998	

Post insertion at 5 min	PROSEAL LMA	30	119.90	12.184	0.021
	ETT	30	129.60	18.689	

Comparison of heart rate for the devices under study proves that there is a significant difference between the usage of device.

SpO2

	Group	**No**	**Mean**	**SD**	**P value**
Baseline	PROSEAL LMA	30	99.43	0.858	0.229
	ETT	30	99.67	0.606	
Pre insertion	PROSEAL LMA	30	99.70	0.651	0.479
	ETT	30	99.80	0.407	
Post insertion at 0 min	PROSEAL LMA	30	99.57	0.728	0.849
	ETT	30	99.60	0.621	
Post	PROSEAL	30	99.77	0.430	

insertion at 1 min	LMA				0.325
	ETT	30	99.87	0.346	
Past insertion at 3 min	PROSEAL LMA	30	99.87	0.346	0.325
	ETT	30	99.77	0.430	
Post insertion at 5 min	PROSEAL LMA	30	99.97	0.179	0.168
	ETT	30	99.77	0.423	

SpO2 were measured preoperatively, before intubation, immediately, first ,third and 5 minutes after intubation.

Statistical analysis by Student's t test reveals P value of 0.229, 0.479, 0.849, 0.325, 0.325 and 0.168 respectively which are not significant.

Hence there was no significant oxygenation difference between two techniques.

Systolic Blood Pressure

	Group	No	Mean	SD	P value
Baseline	PROSEAL LMA	30	122.33	12.291	0.482
	ETT	30	120.13	11.788	
Pre insertion	PROSEAL LMA	30	97.6	10.795	0.299
	ETT	30	100.63	11.619	
Post insertion at 0 min	PROSEAL LMA	30	107.13	12.362	0.035
	ETT	30	114.03	12.389	
Post insertion at 1 min	PROSEAL LMA	30	107.77	9.655	0.028
	ETT	30	113.93	11.486	
Past insertion at 3 min	PROSEAL LMA	30	108.73	8.808	0.002
	ETT	30	116.83	10.446	
Post insertion at 5 min	PROSEAL LMA	30	107.7	7.530	0.001
	ETT	30	115.6	9.547	

Diastolic Blood Pressure

	Group	No	Mean	SD	P value
Baseline	PROSEAL LMA	30	81.40	8.669	0.071
	ETT	30	77.50	7.736	
Pre insertion	PROSEAL LMA	30	63.63	9.246	0.230
	ETT	30	66.13	6.469	
Post insertion at 0 min	PROSEAL LMA	30	65.90	9.045	<0.001
	ETT	30	75.00	6.823	
Post insertion at 1 min	PROSEAL LMA	30	67.80	8.075	0.001
	ETT	30	74.40	6.173	
Post insertion at 3 min	PROSEAL LMA	30	68.13	7.682	<0.001
	ETT	30	76.00	5.736	
Post insertion at 5 min	PROSEAL LMA	30	67.13	4.995	<0.001
	ETT	30	75.33	5.371	

Mean Arterial Pressure

	Group	No	Mean	SD	P value
Baseline	PROSEAL LMA	30	94.98	9.118	0.155
	ETT	30	91.68	8.636	
Pre insertion	PROSEAL LMA	30	74.93	9.045	0.192
	ETT	30	77.81	7.801	
Post insertion at 0 min	PROSEAL LMA	30	79.72	8.529	<0.001
	ETT	30	87.98	7.887	
Post insertion at 1 min	PROSEAL LMA	30	81.07	7.943	0.002
	ETT	30	87.54	7.046	
Post insertion at 3 min	PROSEAL LMA	30	81.64	7.269	<0.001
	ETT	30	89.57	6.335	
Post insertion at 5 min	PROSEAL LMA	30	80.62	4.983	<0.001
	ETT	30	88.72	5.864	

There is a highly significant difference in comparison of post – intubation systolic blood pressure, diastolic blood pressure, mean arterial pressure values of endotracheal tube and Proseal LMA

Table: 13 Blood staining of devices

Group	No	Blood staining				P value
		Yes	%	No	%	
PROSEAL LMA	30	0	-	30	100	Not applicable
ETT	30	0	-	30	100	

Blood staining was not noted with any of the devices.

Hence there is no incidence of airway trauma in both the groups.

Table: 14 Incidence of complications

	Group	No	Yes		No		P value
Hoarseness of voice	PROSEAL LMA	30	0	-	30	100	0.002
	ETT	30	8	26.7	22	73.3	
Laryngospasm	PROSEAL LMA	30	1	3.3	29	96.7	0.313
	ETT	30	0	-	30	100	

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Laryngospasm occurred in 1/30 in PROSEAL LMA group and not seen in ETT group. Statistical analysis reveals P Value of 0.313 which is not significant.

Hoarseness of voice did not occur with Proseal LMA group and seen in 8/30 children in ETT group. Statistical analysis reveals P Value of 0.002 which is significant.

DISCUSSION

Maintenance of a patent airway is essential for adequate oxygenation and ventilation and failure to do so, even for a brief period of time, can be life threatening. Difficult direct laryngoscopy and intubation occurs in 1.5–8.5% whereas failed intubation occurs in 0.13–0.3% of general anesthetics in children. The unanticipated difficult airway occurs with a low and consistent incidence in anesthesia practice and represents a complex interaction between children factors, the clinical setting, and the skills of the practitioner .Therefore, identification of children with difficult airway is vital in planning the anesthetic management so that endotracheal intubation can be achieved safely. Pediatric airway is known to be more difficult to manage than adult airway due to anatomical variations. The margin of safety and therefore risk of morbidity is higher if the airway is complicated or difficult in children.

PROSEAL LMA is being successfully used to maintain airway, the rapid and easy insertion, safety provided by the gastric channel, low post operative complications and high seal pressure provide benefit to both the clinician and the children.

Study by Mamta G Patel , VN Swaden , Geetika bansal published in Indian journal of Anaesthesiology showed effective airway time were similar in both the groups,[31+4.61 seconds], but our study showed a significant difference in

effective airway time [5.4 seconds] which might be due to absence of direct laryngoscopy in Proseal group.

The success rate of placement of Proseal LMA in the first attempt was 83 % in the study conducted by Lalwani et al. Our study showed a success rate of 100 % because of prior experience with the device.

Study by Lopez et al showed that gastric tube insertion were successful in the first attempt in 106/120 children. Our study also showed a similar success rate. The 8 Fr gastric tube is more suited to pass through the drain channel of size 2 LMA than the 10 Fr gastric tube as per manufacturer recommendations.

Endotracheal intubation causes profound hemodynamic changes than the placement of Proseal LMA as the latter does not invade the trachea.

There were no change in hemodynamic parameters in Proseal LMA group prior to and after the insertion of the airway device , while there were a statistically significant difference with the use of endotracheal tube value <0.01. Studies by Mamta et al and Lalwani et al also showed similar results.

Brimacombe et al studied advantage of LMA over tracheal tube and concluded that LMA is easier to insert, has reduced requirement of anaesthesia for airway

tolerance, lower frequency of coughing during emergence and lower incidence of sore throat in adults.

Arterial o 2saturation remained unchanged throughout the study in both the groups.Goldman et al studied the proseal LMA for pressure controlled ventilation in pediatric patients and concluded and Pao2 was higher with Proseal LMA when PEEP was used.

Supraglottic airway devices could be less irritating to the upper or the lower airway and associated with less laryngeal stimulation leading to less significant post operative complications. Blood staining of the airway device was not noted in any of the children. There was no incidence of aspiration in either group of children during induction of anaesthesia, in intraoperative period or after the removal of respective airway device.

Hoarseness of voice were noted in 8 children in the ETT group along with coughing which were statistically significant p value <0.001.

In our study we did come across Laryngospasm in one children belonging to the Proseal group which were not significant. However Alan et al noted the above complications in their study.

Brimacombe et al compare the performance of size 2 and size 3 Proseal LMA and concluded that the first time and overall insertion success rate was 84 % and 100%.

SUMMARY

The endotracheal tube has long been used as an effective airway in pediatric patients requiring general anesthesia. The disadvantages of using the endotracheal tube are hemodynamic responses following intubation, post extubation coughing and hoarseness. These can be overcome by using the Proseal LMA which has a drain tube to drain away stomach contents and can provide a safe and effective alternative to endotracheal tube in terms of ventilatory efficacy and maintenance of oxygen saturation.

We conducted a study to compare the Proseal LMA and endotracheal tube in 60 pediatric patients. Anaesthesia induction and maintenance was similar in both the groups. They were compared for differences in effective airway time, hemodynamic responses following the use of the airway device and post extubation complications.

The results of the study are as follows:

1. The Proseal LMA takes a significantly shorter time to insert than the endotracheal tube due to insertion technique which does not involve a direct laryngoscopy.

2. The changes in hemodynamic responses following insertion were higher in the endotracheal group.
3. The 8 Fr gastric tube can be easily passed through the Proseal LMA than the 10 Fr size which is recommended by the manufacturer.
4. The incidence of coughing and post operative sore throat is higher with the use of endotracheal tube .These complications occurred less frequently in the Proseal LMA group.

CONCLUSION

PROSEAL LMA is a safe and suitable airway device in pediatric children as judged by stable hemodynamics, good oxygenation, adequate ventilation and lesser incidence of postoperative complications. Hence we can conclude that PLMA can be used as a safe and effective airway device to endotracheal intubation in children undergoing general anaesthesia

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PROFORMA

DATE: ROLL NO: AIRWAY DEVICE:

NAME:

AGE: SEX: IP NO:

DIAGNOSIS:

SURGICAL PROCEDURE DONE:

Ht: CVS: HB:

Wt: RS:

Airway:

PRE OP ASSESSMENT:

HISTORY: Any comorbid illness

H/o documented difficult airway

H/o previous surgeries

Measures of study outcome:

INTUBATION RESPONSE:

	HR	SBP	DBP	MAP	SPO2
PRE OP					
PRE INTUBATION					
POST INTUBATION					
POST INTUBATION					

1 MIN

3 MIN

5 MIN

NO OF ATTEMPTS

INSERTION TIME

NO OF ATTEMPTS AT RYLE ‘ S TUBE INSERTION

COMPLICATIONS AT EXTUBATION:

COUGHING

LARYNGOSPASM

BLOOD STAINING OF ET TUBE/ PROSEAL LMA

TONGUE/LIP/DENTAL TRAUMA

HOARSENESS

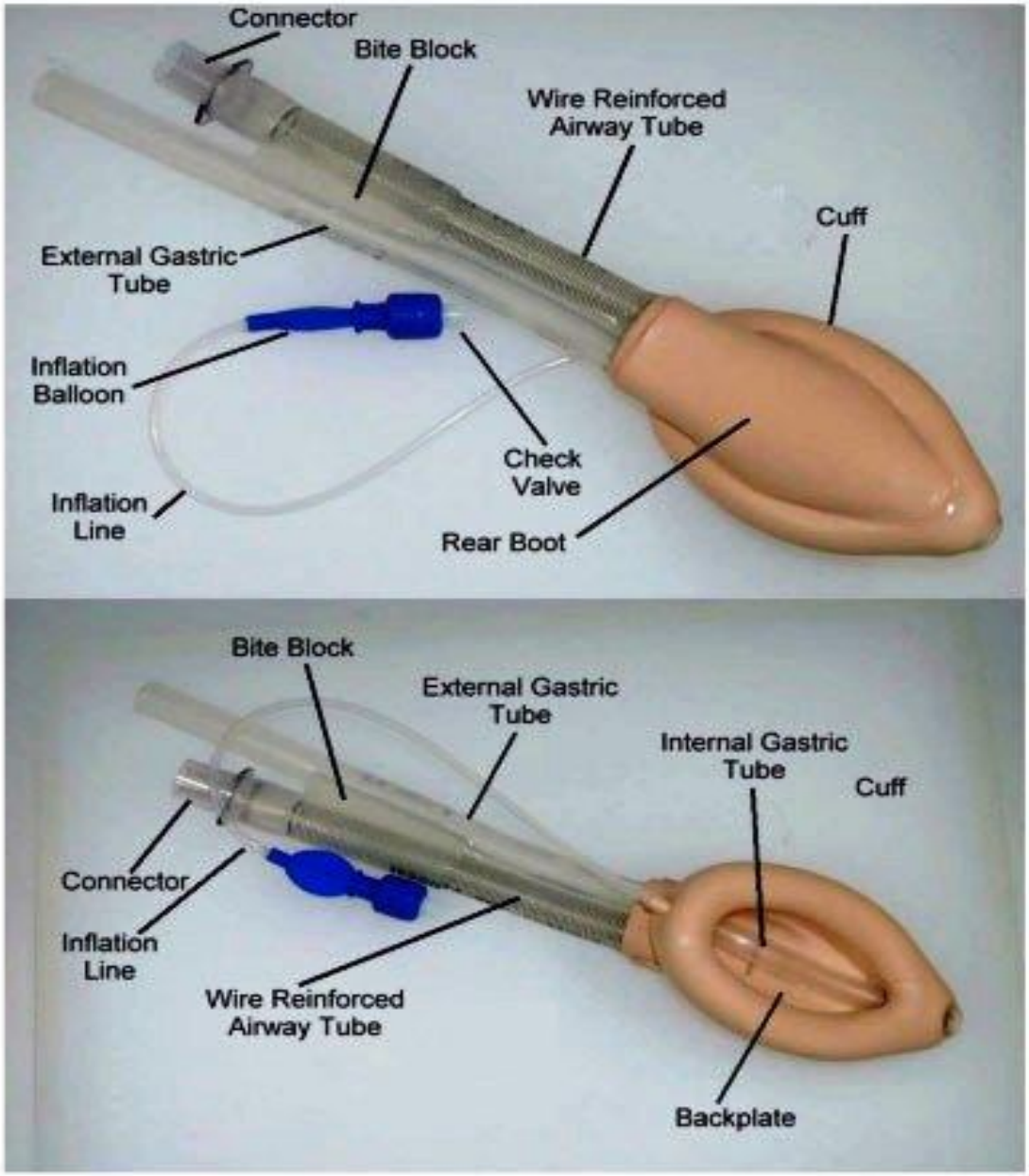
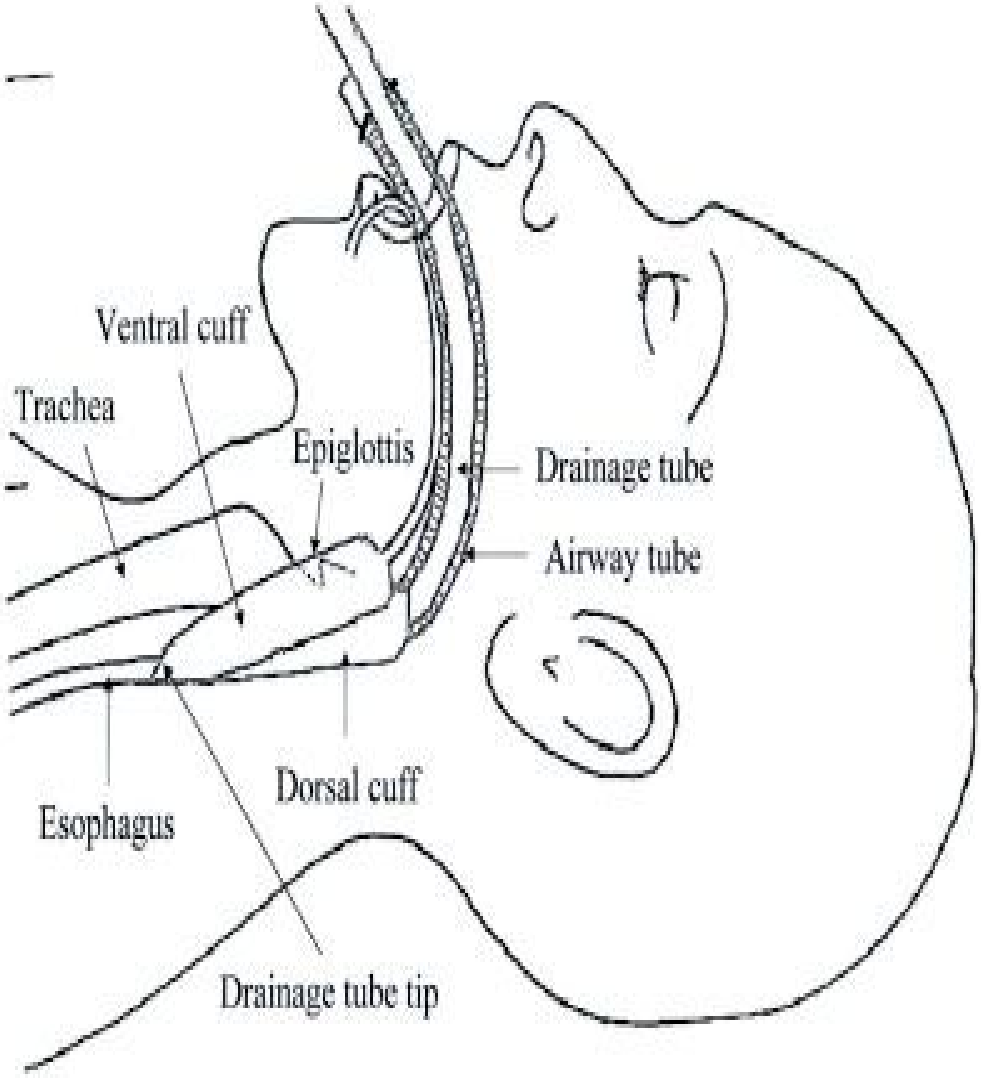
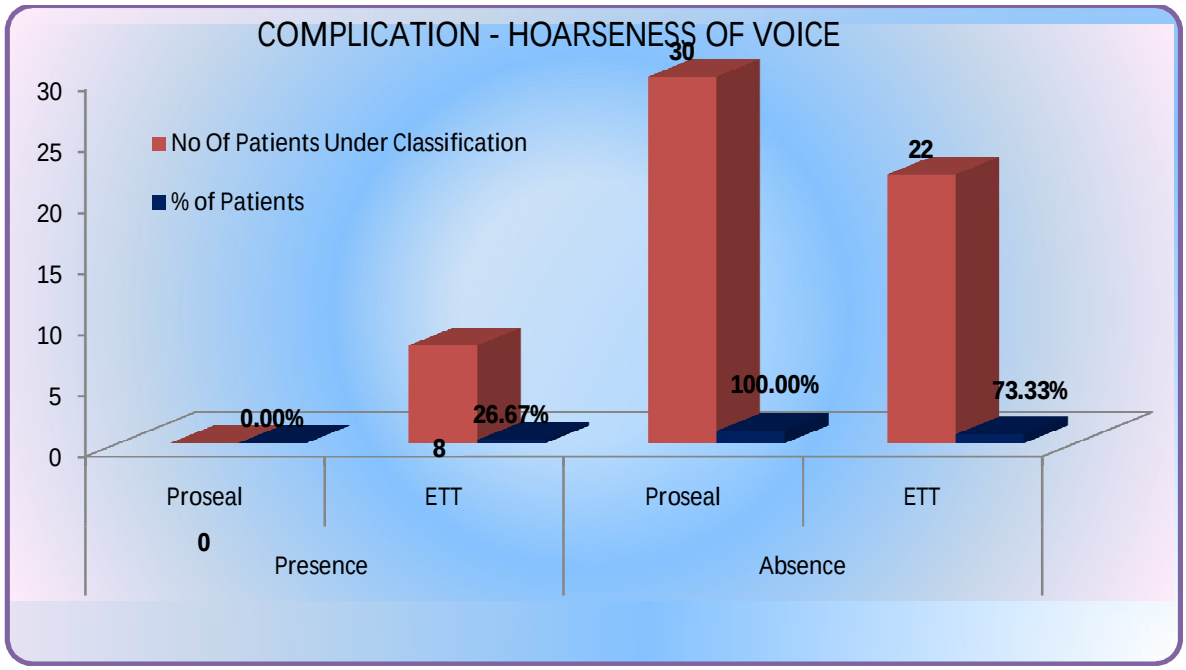
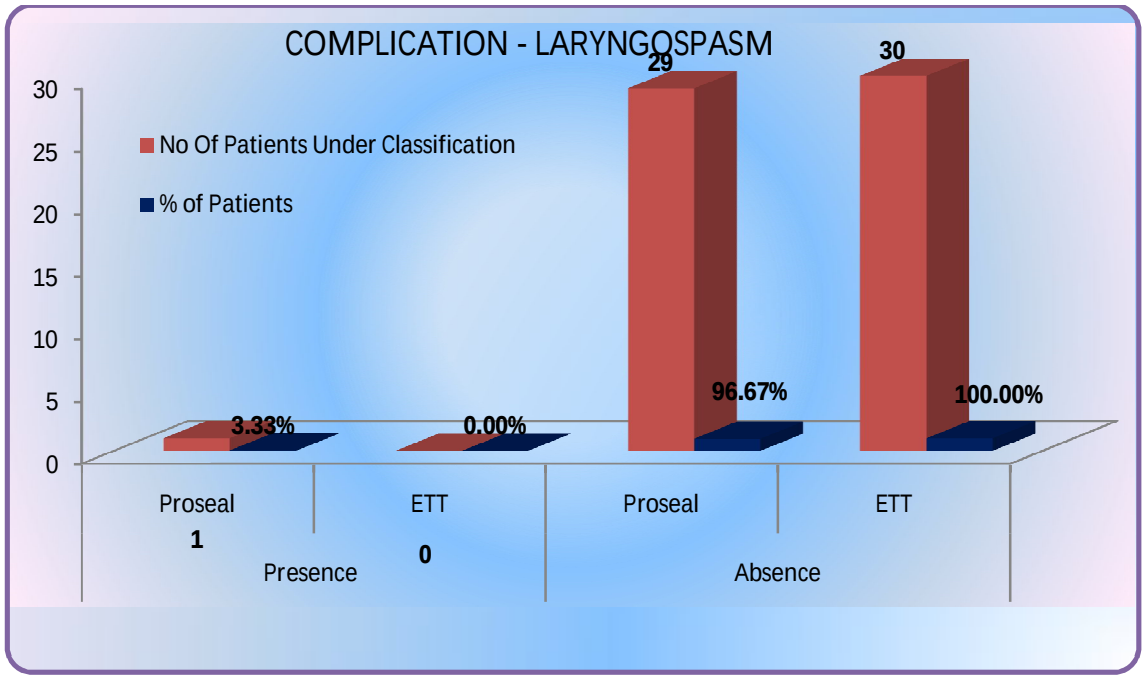
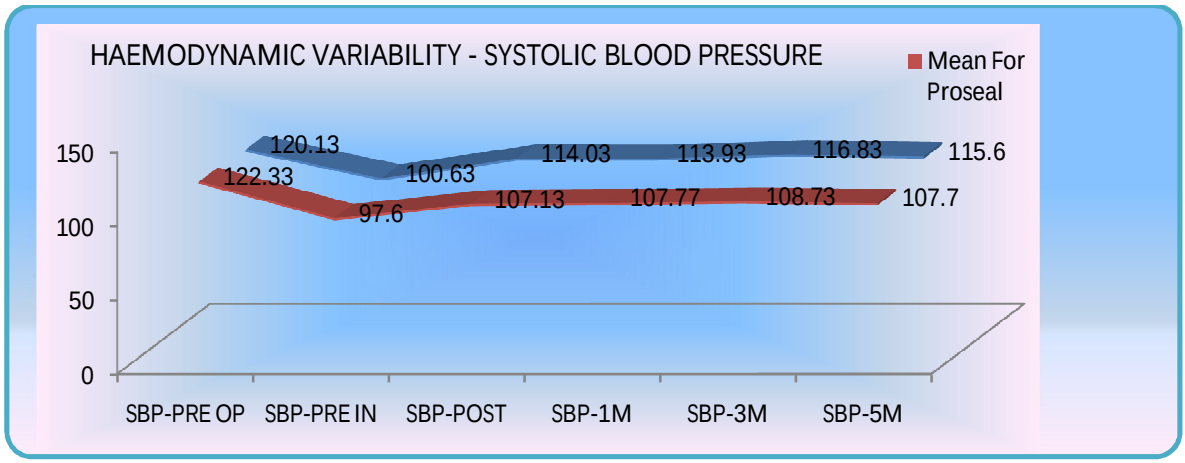

Connector
Bite Block
Wire Reinforced Airway Tube
Cuff
External Gastric Tube
Inflation Balloon
Check Valve
Inflation Line
Rear Boot
Bite Block
External Gastric Tube
Internal Gastric Tube
Cuff
Connector
Inflation Line
Wire Reinforced Airway Tube
Backplate

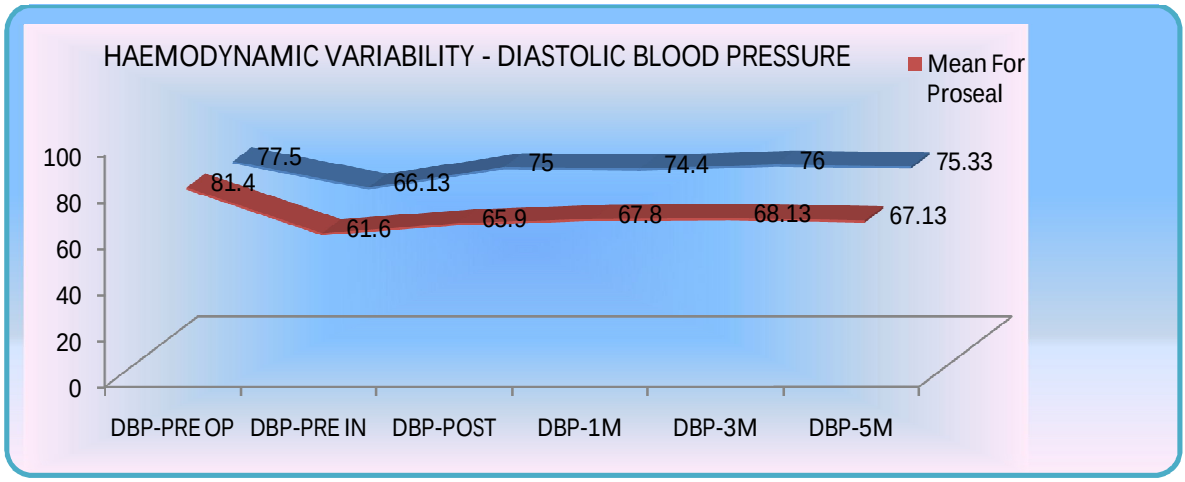
Illustration of the ProSeal LMA when correctly seated.

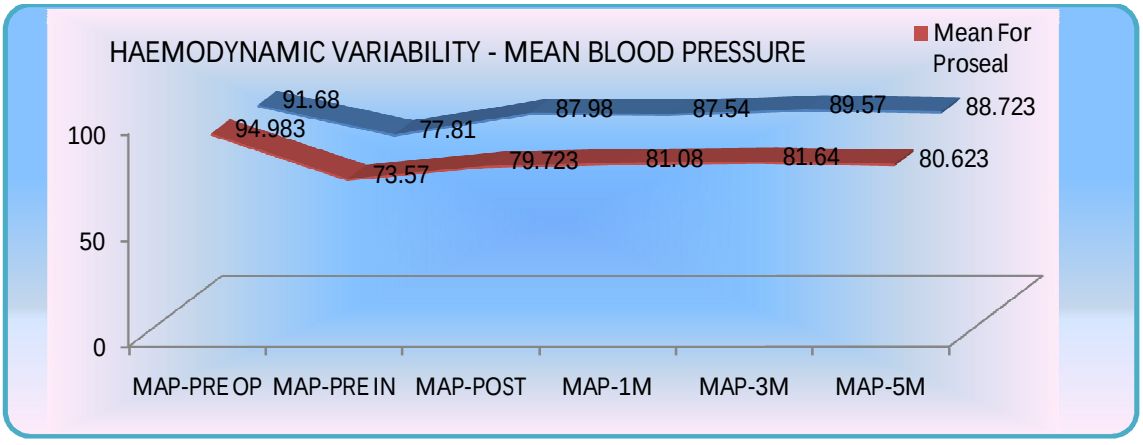


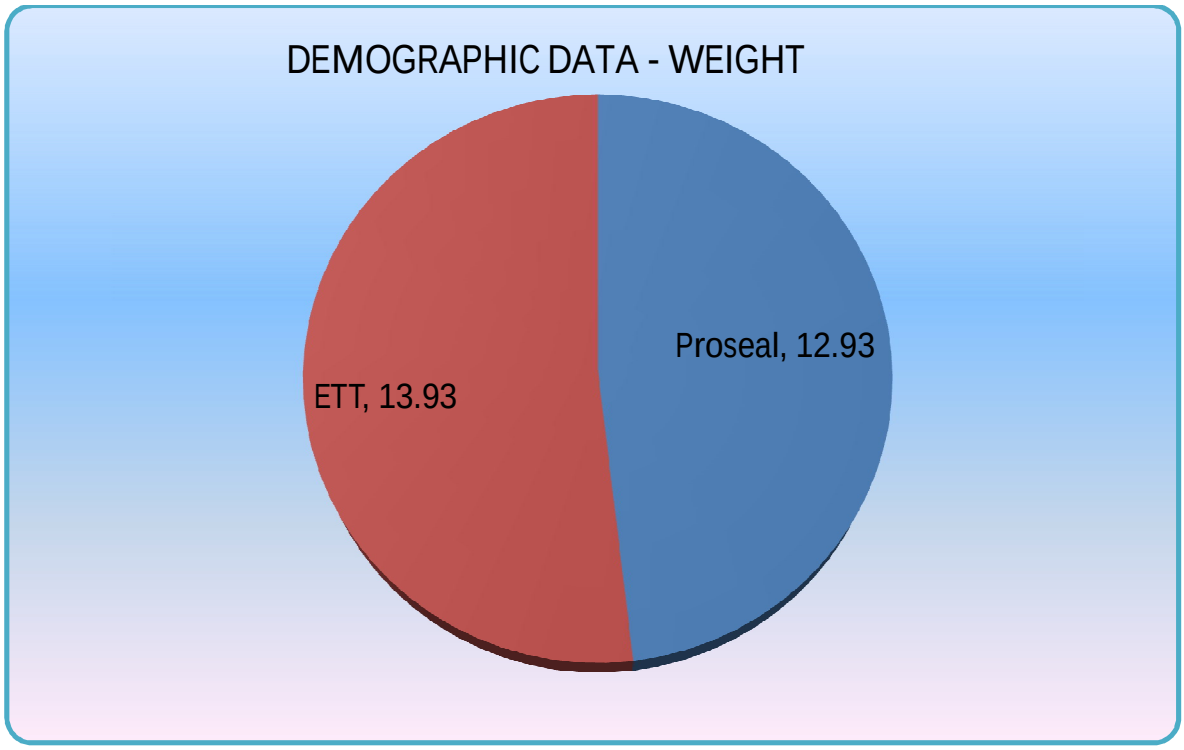

COMPLICATION - HOARSENESS OF VOICE
30
25
20
15
10
5
0
No Of Patients Under Classification
% of Patients
0.00%
26.67%
8
100.00%
30
73.33%
22
Proseal
ETT
Proseal
ETT
0
Presence
Absence

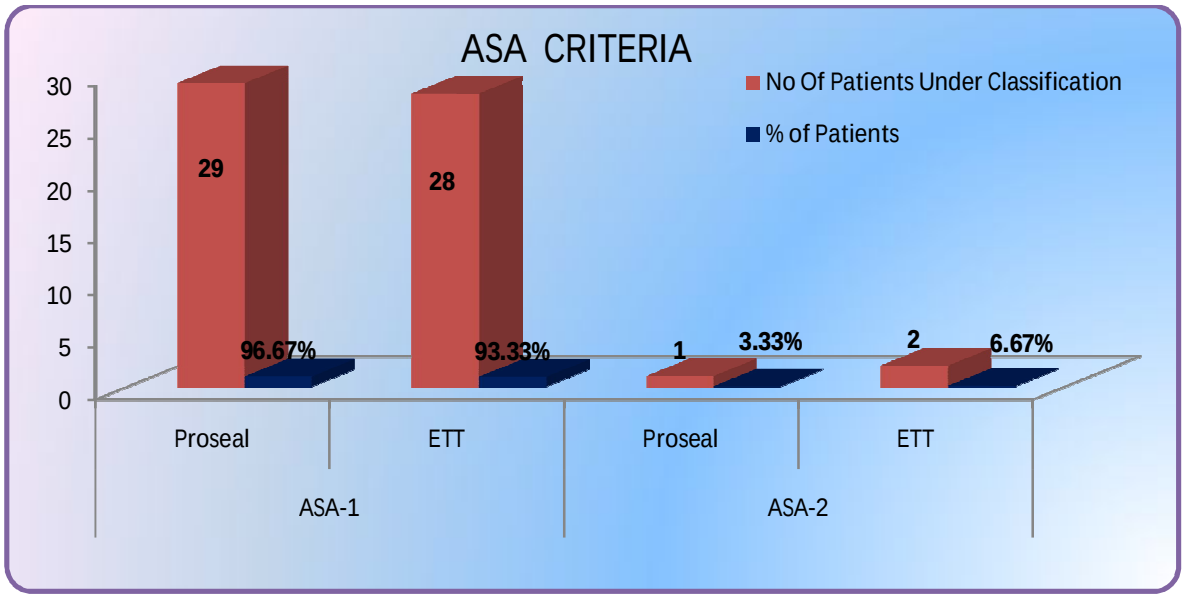

COMPLICATION - LARYNGOSPASM
30
25
20
15
10
5
0
No Of Patients Under Classification
% of Patients
3.33%
0.00%
29
96.67%
30
100.00%
Proseal
ETT
Proseal
ETT
1
0
Presence
Absence

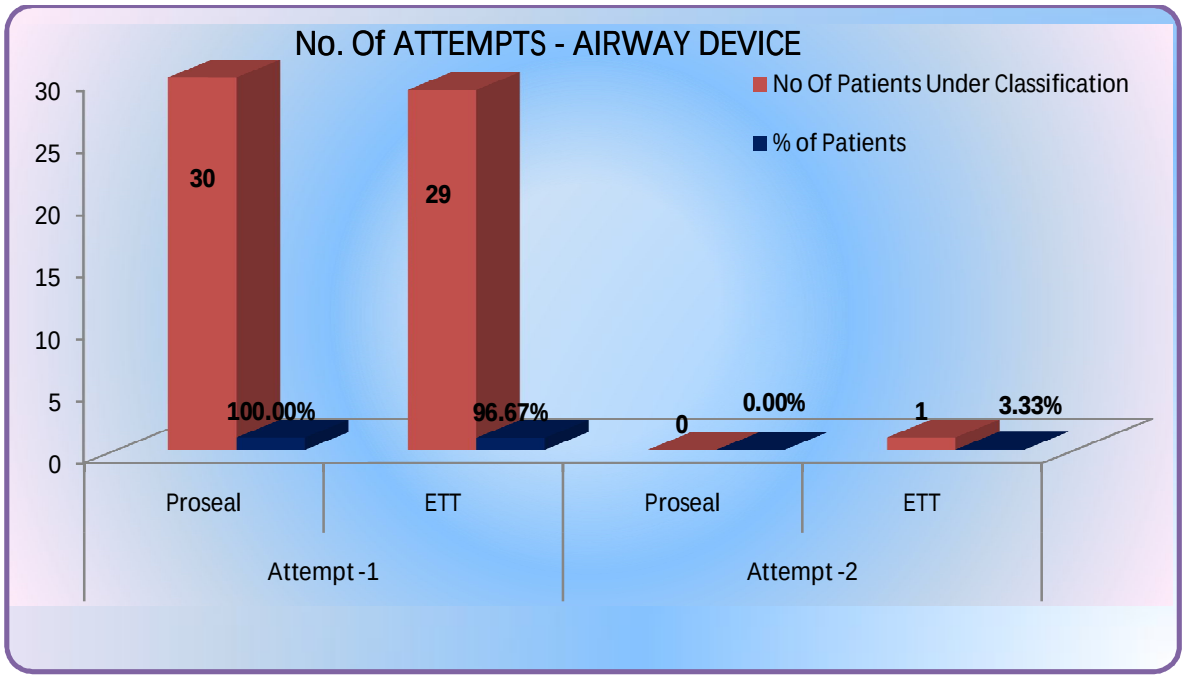

HAEMODYNAMIC VARIABILITY - SYSTOLIC BLOOD PRESSURE
Mean For Proseal
150
100
50
0
120.13
100.63
114.03
113.93
116.83
115.6
122.33
97.6
107.13
107.77
108.73
107.7
SBP-PRE OP
SBP-PRE IN
SBP-POST
SBP-1M
SBP-3M
SBP-5M

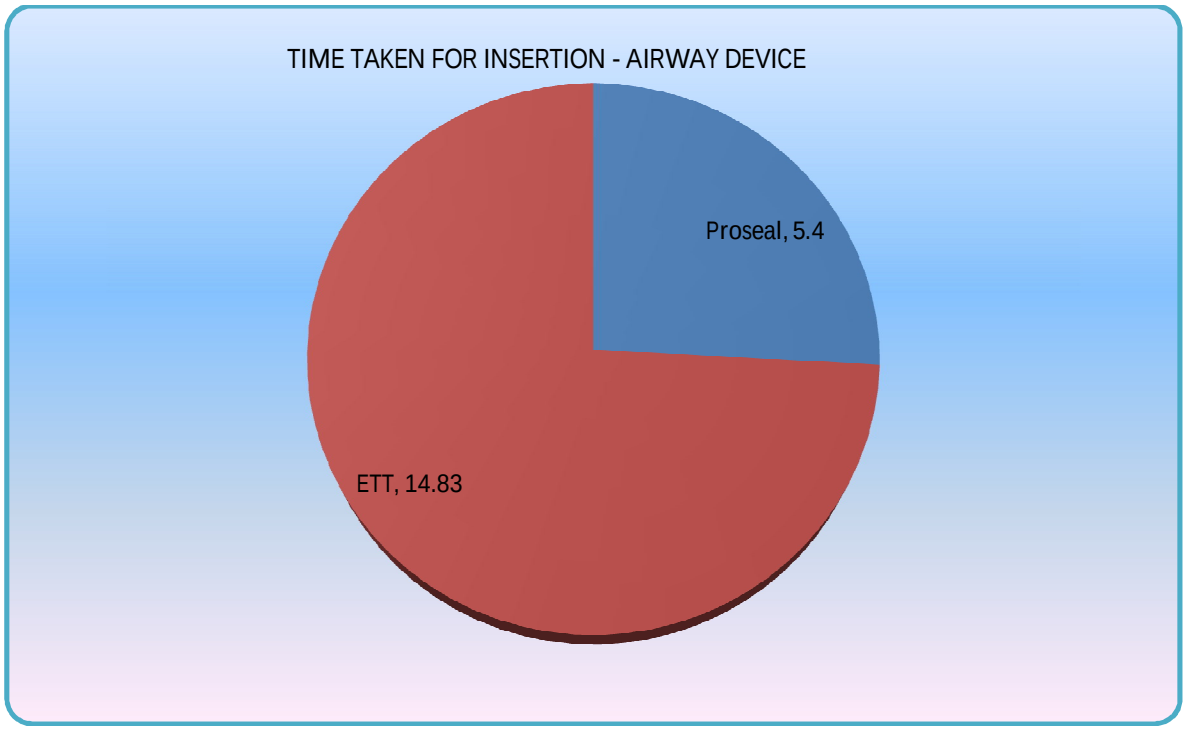

HAEMODYNAMIC VARIABILITY - DIASTOLIC BLOOD PRESSURE
Mean For Proseal
100
80
60
40
20
0
77.5
66.13
75
74.4
76
75.33
81.4
61.6
65.9
67.8
68.13
67.13
DBP-PRE OP
DBP-PRE IN
DBP-POST
DBP-1M
DBP-3M
DBP-5M

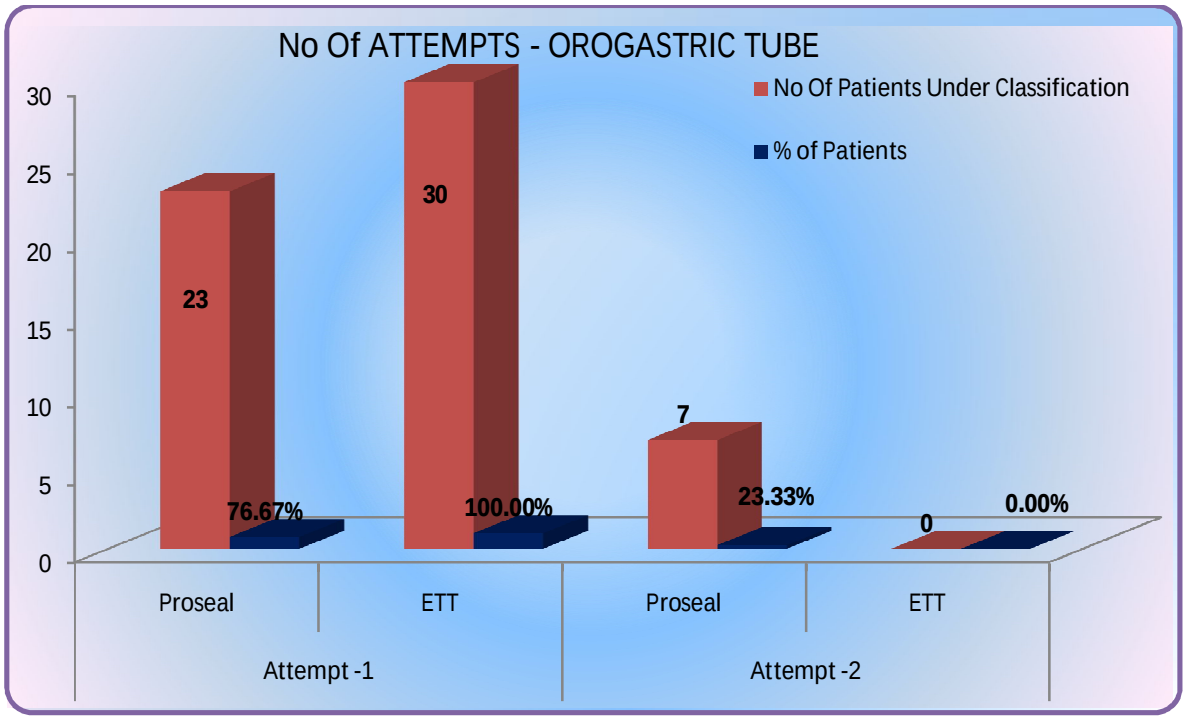

HAEMODYNAMIC VARIABILITY - MEAN BLOOD PRESSURE
Mean For Proseal
100
50
0
91.68
77.81
87.98
87.54
89.57
88.723
94.983
73.57
79.723
81.08
81.64
80.623
MAP-PRE OP
MAP-PRE IN
MAP-POST
MAP-1M
MAP-3M
MAP-5M

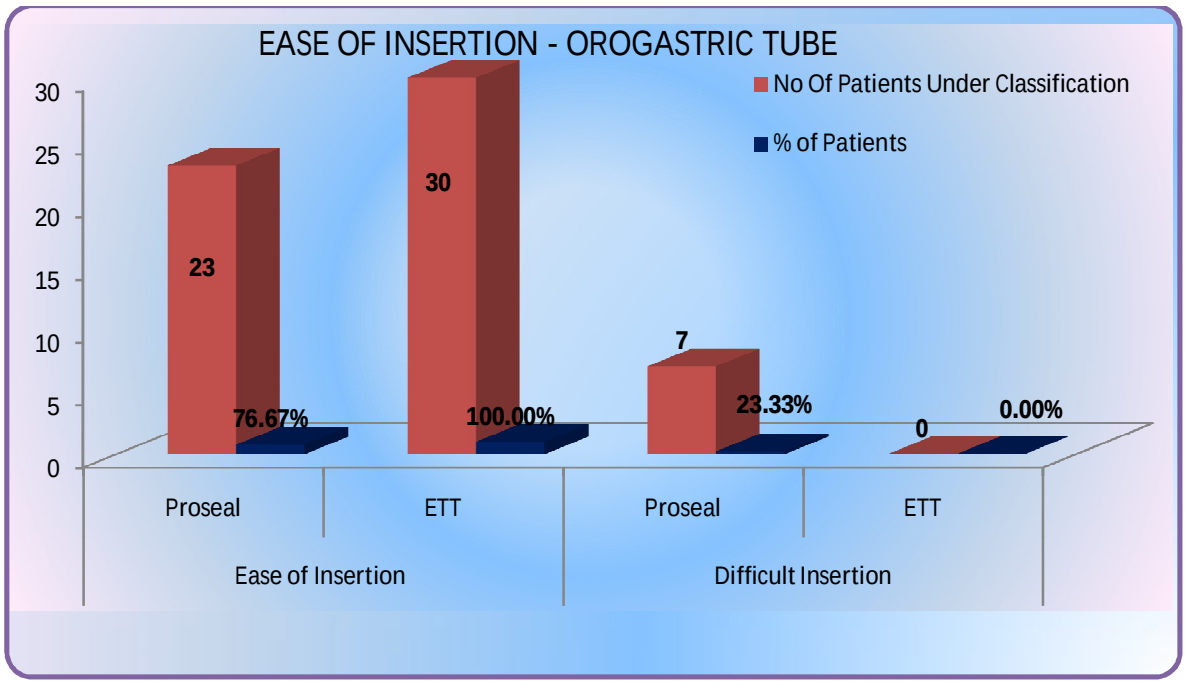

DEMOGRAPHIC DATA - WEIGHT
Proseal, 12.93
ETT, 13.93


ASA CRITERIA
No Of Patients Under Classification
% of Patients
30
25
20
15
10
5
0
29
96.67%
28
93.33%
1
3.33%
2
6.67%
Proseal
ETT
Proseal
ETT
ASA-1
ASA-2


No. Of ATTEMPTS - AIRWAY DEVICE
No Of Patients Under Classification
% of Patients
30
25
20
15
10
5
0
30
29
0
1
100.00%
96.67%
0.00%
3.33%
Proseal
ETT
Proseal
ETT
Attempt -1
Attempt -2


TIME TAKEN FOR INSERTION - AIRWAY DEVICE
Proseal, 5.4
ETT, 14.83


No Of ATTEMPTS - OROGASTRIC TUBE
No Of Patients Under Classification
% of Patients
30
25
20
15
10
5
0
23
30
7
0
76.67%
100.00%
23.33%
0.00%
Proseal
ETT
Proseal
ETT
Attempt -1
Attempt -2


EASE OF INSERTION - OROGASTRIC TUBE
No Of Patients Under Classification
% of Patients
30
25
20
15
10
5
0
23
30
7
0
76.67%
100.00%
23.33%
0.00%
Proseal
ETT
Proseal
ETT
Ease of Insertion
Difficult Insertion

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3

Telephone No: 04425305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To

Dr. Charulatha .R
PG in MD Anaesthesia
Madras Medical College, Chennai -3.

Dear Dr. Charulatha .R

The Institutional Ethics Committee of Madras Medical College reviewed and discussed your application for approval of the proposal entitled " Prospective randomized comparison of proseal LMA and Endotracheal Tube for airway management in children under general Anaesthesia" No. 07022011.

The following members of Ethics Committee were present in the meeting held on 17.02.2011 conducted at Madras Medical College, Chennai -3.

1.	Prof. S.K. Rajan, MD	– Chairperson
2.	Prof. A. Sundaram, MD Dean i/c , Madras Medical College, Chennai -3	– Member Secretary
3.	Prof R. Sathianathan Director , Institute of Psychiatry, MMC,Ch-3	– Member
4.	Prof R. Nandhini, MD Director, Institute of Pharmacology, MMC, Ch-3	– Member
5.	Prof. Pregna B. Dolia MD Director , Institute of Biochemistry, MMC, Ch-3	– Member
6.	Prof. C. Rajendiran .MD Director , Institute of Internal Medicine, MMC, Ch-3	– Member
7.	Prof. Geetha Subramanian, MD,DM Prof. & Head , Dept. of Cardiology, MMC, Ch-3	– Member
8.	Thiru. A. Ulaganathan Administrative Officer, MMC, Chennai -3	– Layperson
9.	Thiru. S. Govindasamy . BA.BL	– Lawyer
10.	Tmt. Arnold Soulina	– Social Scientist

We approve the proposal to be conducted in its presented form.

Sd /. Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information / informed consent and asks to be provided a copy of the final report

Member Secretary, Ethics Committee